Individual Safety Report

3393694-3-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

I Pharmaceutical Company

Approved by FDA on 3/22/94

Mfr report # USA000685

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: 44 yrs or Date of birth: [redacted]
3. Sex: ☒ female ☐ male
4. Weight: ____ lbs or 86.184 kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 12/??/97

4. Date of this report (mo/day/yr): 01/15/99

5. Describe event or problem

Increased liver enzymes, aching legs, nervousness, increased blood pressure, not sleeping well

A 44-year-old female consumer has been on Vicodin ES (one tablet prn up to six times per day) on & off since 1995 reports developing "withdrawal symptoms" since discontinuing therapy on 03-Jan-1998. She has had aching legs, nervousness, an increased blood pressure and trouble sleeping since therapy discontinuation. At the time of reporting (28-Jan-1998) the events are ongoing, but have improved. Elevated liver enzymes were noted in Dec-1997. Consumer discussed events with her physician, but did not provide physician contact information.

6. Relevant tests/laboratory data, including dates

elevated liver enzymes in Dec-1997 (exact labs and values unspecified)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

allergic to Compazine
Concomitant disease(s): hypertension
Race: UNK

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 VICODIN ES
#2

2. Dose, frequency & route used
#1 1 TAB PRN PO
#2

3. Therapy dates (if unknown, give duration)
#1 ??-???-95 to 03-JAN-98
#2

4. Diagnosis for use (indication)
#1 back pain
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 UNKNOWN
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
#1 NI #2

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: atenolol Dates: ??-???-97 to NA
Name: NORVASC Dates: ??-???-97 to NA
Name: DYAZIDE Dates: ??-???-97 to NA

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
Knoll Pharmaceutical Company
3000 Continental Drive - North
Mount Olive, New Jersey 07828-1234

2. Phone number: (973) 426-2600

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☒ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

UNITED STATES

4. Date received by manufacturer (mo/day/yr): 01/28/98

5. (A)NDA # 89-736
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☐ 15-day
- ☐ 10-day ☒ periodic
- ☒ Initial ☐ follow-up # ____

8. Adverse event term(s)
HEPATIC FUNCTION ABNORMAL NOS, PAIN IN LIMB, NERVOUSNESS, BLOOD PRESSURE INCREASED, INSOMNIA, DRUG WITHDRAWAL SYNDROME

9. Mfr. report number
USA000685

E. Initial reporter

1. Name, address & phone #
[redacted] Rd.
[redacted] USA
Phone: [redacted]

FEB 16 1999

2. Health professional? ☐ yes ☒ no

3. Occupation: CONSUMER

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: FIORICET Dates: 03-JAN-98 to NA

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